

## **Mycobacterium Tuberculosis Direct Test (MTD) Information Sheet and Approval Criteria for Testing at the South Dakota State Public Health Laboratory (Effective 4-30-2004)**

The Mycobacterium Tuberculosis Direct (MTD) test is now available for select specimens at the South Dakota State Public Health Laboratory. The MTD test is an amplified test for the detection of *M. tuberculosis* in both smear-positive and smear-negative clinical specimens. It is currently only approved for pulmonary specimens. The MTD test is currently the most rapid technique for diagnosing tuberculosis as the results are usually available the same day the test is performed. A positive MTD result indicates a high likelihood of TB however, a negative result does not exclude a TB diagnosis. Therefore results from the MTD test must be interpreted in the context of the patient's signs and symptoms as well as the prevalence of TB within the community. The MTD test does not replace the need for routine AFB smear and culture and should not replace clinical judgment or be relied on as the ONLY guide for therapy initiation or isolation practices. The MTD test detects nucleic acids from dead as well as live *M. tuberculosis*. Therefore, this testing method should be used only for initial diagnosis and not follow-up evaluation of patients who are receiving treatment for active TB.

### **MTD TEST APPROVAL CRITERIA**

Due to cost of the test, the State Public Health Laboratory and the TB Control Program have established the following approval criteria for specimens. All specimens must meet all of the criteria listed below:

1. **Pre-approval by State Lab or TB Program.** The MTD test is available by request only. All specimens must be approved in advance by telephoning the State Lab (773-3368) or the TB Program (773-3737). State Lab and/or TB Program personnel will consider all of the approval criteria as well as the public health need for paying for the test based on the specific circumstances of the individual patient.  

**AND**
2. **Patient must be suspected of having TB.** All MTD tests done at the State Lab will be for patients who are considered by their physician to have a high suspicion of TB disease. Therefore all patients will be reported to the TB Control Program as suspect TB cases so the patient can be tracked.  
**("The MTD test should ONLY be used when the clinician has an intermediate or high suspicion of TB disease in which case the sensitivity is 75-88% and the specificity is 100%". Source: 2000 American Thoracic Society (ATS) – Diagnostic Standards and Classification of TB in Adults and Children).**  

**AND**
3. **Patient is AFB positive OR meets clinical criteria.** The patient must be either AFB positive by direct smear OR have a combination of 2 or more of the following:
  - (a) Radiological evidence of current TB disease
  - (b) 2 or more anti-TB medications have been initiated
  - (c) Positive TB skin test
  - (d) Contact to infectious TB case

If approved, only one pulmonary specimen per patient will be accepted. Acceptable source material (i.e. sputum, bronch wash) must be submitted and received within 3 days of collection. For those laboratories doing primary culturing, treated specimens will be accepted if treated within 3 days of collection and held in frozen state. Laboratory results will be reported by telephone the same day the test is completed. All non-pulmonary specimens as well as any pulmonary specimens that were not pre-approved that are subsequently submitted to the State Lab will be billed to the submitter, if tested, at a cost of \$256.00 per specimen. The State Public Health Laboratory retains the right to determine whether or not MTD testing will be conducted on these specimens based on available staffing. Questions concerning this test should be directed to the State Public Health Laboratory staff at (605) 773-3368 or the TB Control Program staff at (605) 773-3737.